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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/826,230

04/16/2004

Robert A. Ray

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9658

30448

7590

03/11/2008

AKERMAN SENTERFITT

P.O. BOX 3188

WEST PALM BEACH, FL 33402-3188

EXAMINER

CHAN, CEDRIC A

ART UNIT

PAPER NUMBER

4151

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DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/826,230	Applicant(s) RAY ET AL.	
	Examiner Cedric A. Chan	Art Unit 4151	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 April 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 April 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Drawings

1. The drawings are objected to because figure labels are hand-written in Figures 1 and 2. The drawing in Figure 3 is unlabeled, and it is unclear what the various components depicted in Fig. 3 are intended to represent with respect to the present invention. Figs. 4A-4D contain hand-written labels which may be illegible. Fig. 6 contains hand-written labels which may be illegible. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

2. The claims filed on April 16, 2004 does not comply with the requirements of 37 CFR 1.121(c) because a complete listing of all claims along with intended claim cancellations is not

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provided. Applicant is reminded that claims filed on or after July 30, 2003 must comply with 37 CFR 1.121(c).

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. **Claims 13-18** are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. The term "relatively rigid" in claim 13, line 4 is a relative term which renders the claim indefinite. The term "relatively rigid" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).
9. **Claims 13-14 and 16-18** are rejected under 35 U.S.C. 103(a) as being unpatentable over Gauntley et al. (US 4,159,193).

Gauntley et al. teach a method for urine analysis (see Abstract) comprising the steps of: providing a urine sample collecting device including a paper test strip (i.e., collection pad) (see Col. 7, lines 54-65), applying a liquid urine sample to the test strip (see Col. 8, lines 25-33), allowing the test strip to dry (see Col. 8, lines 45-50), transporting the device to a laboratory for analysis (see Col. 8, lines 37-42; see also Col. 2, line 20), eluting the affixed metabolites from the test strip (see Col. 8, lines 65-68 and Col. 9, lines 1-2; see also Col. 2, lines 24-25), and determination of the presence of various analytes (see, for example, "ALA determination" and "Determination of creatinine" in Col. 9).

The collection device of Gauntley et al. comprises a relatively rigid paper strip (see Col. 8, lines 1-5) forming a handle member having a handle end (see Fig. 4, #5) and a collection end (see fig. 4, #11), said collection end having a collection pad (11) for collecting and drying the sample containing the analyte, said collection pad capable of having at least a portion thereof

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removed from the device to recover the analyte for detection or measurement by laboratory analysis (see Col. 8, lines 12-15).

Gauntley et al. do not specifically teach the step of “reporting results of the analysis to the individual or health care professional.” However, it would have been obvious to one of ordinary skill in the art to disclose the results of analysis as required, in order for the individual or healthcare professional to be aware of the health condition of the patient.

Regarding claim 14, Gauntley et al. teach drying the test strip prior to cutting the strip at a defined reference mark (see Col. 8, lines 54-56).

Regarding claim 16, Gauntley et al. teach different elution methods, depending on the type of analyte being eluted. For example, in the analysis of urinary ALA and creatinine, Gauntley et al. teach elution by immersing the test strip in 1 M acetate buffer pH 4.6 (see Col. 8, lines 66-68). Gauntley et al. use 0.2 M phosphate buffer (pH 6) for the elution of trichloroacetic acid, and trichloroethanol from urine.

Regarding claim 17, Gauntley et al. teach using different methods for analyzing different analytes, as discussed above and further described in Examples 1 and 2 (Cols. 9 and 10).

Regarding claim 18, the test strip of Gauntley et al. is impregnated with non-activated resin (see Col. 8, lines 5-6).

10. **Claim 15** is rejected under 35 U.S.C. 103(a) as being unpatentable over Gauntley et al. (US 4,159,193) in view of Macri (US 5,252,489).

Gauntley et al. teach the limitations of claim 13 as previously discussed, however they do not specifically disclose identifying the individual and sample by a code.

Macri teaches a method for detecting fetal Down syndrome (see Abstract) wherein blood samples are taken from a patient and dried on a specimen collection card (see Col. 6, lines 30-35). Macri also specifically teaches providing the front of the specimen collection card with pre-printed locations for a technician or nurse to enter information, i.e. the patient's identification number, birth date, etc. (see Col. 6, lines 50-56 & 63-67).

It would have been obvious to one of ordinary skill in the art to modify the method taught by Gauntley et al. by providing coded patient information as taught by Macri, because doing so would prevent mishandling of patient samples and misreporting of results upon analysis.

Conclusion

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Lee (US 4,260,392) teaches a method and an apparatus for obtaining an aliquot of a liquid in a gel medium utilizing a collection device comprising a rigid strip with a handle and a collection end, with a collection pad capable of having at least a portion thereof removed from the device, wherein the collection pad is substantially non-reactive.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cedric A. Chan whose telephone number is (571)270-3721. The examiner can normally be reached on Monday-Thursday 8:00 AM - 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Kornakov can be reached on (571) 272-1303. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/C.C./

March 03, 2008

/Michael Kornakov/

Supervisory Patent Examiner, Art Unit 4151